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FROMMER LAWRENCE & HAUG 745 FIFTH AVENUE- 10TH FL.			SALVOZA, M	I FRANCO G
NEW YORK, NY 10151			ART UNIT	PAPER NUMBER
			1648	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)		
	10/706,892	SHI ET AL.		
Office Action Summary	Examiner	Art Unit		
	M. Franco Salvoza	1648		
The MAILING DATE of this communication app Period for Reply	ears on the cover sheet with the c	orrespondence address		
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING DA  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period w  - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION  16(a). In no event, however, may a reply be tin  17/11/11/11/11/11/11/11/11/11/11/11/11/1	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).		
Status	·			
Responsive to communication(s) filed on <u>05 Secondary</u> This action is <b>FINAL</b> . 2b)⊠ This      Since this application is in condition for alloward closed in accordance with the practice under Expression is the practice under Expression in the practice un	action is non-final.  nce except for formal matters, pro			
Disposition of Claims				
4)	<u>8 and 63-65</u> is/are withdrawn from 66-69,93,95 and 96 is/are rejecte	n consideration.		
Application Papers				
9) The specification is objected to by the Examiner 10) The drawing(s) filed on is/are: a) access applicant may not request that any objection to the conference of the	epted or b) objected to by the I drawing(s) be held in abeyance. See ion is required if the drawing(s) is ob	e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d).		
Priority under 35 U.S.C. § 119	·			
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>				
Attachment(s)  1) Notice of References Cited (PTO-892)  2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  3) Information Disclosure Statement(s) (PTO/SB/08)  Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	ate		

### **DETAILED ACTION**

Claims 3, 4, 7, 10, 12, 13, 15, 30 have been amended.

Claims 2, 18, 19, 22-27, 33-44, 70-92 and 94 have been canceled.

New claims 95, 96 have been added.

Applicant elected species "replicon" in the Election dated February 8, 2006. The cDNA clone and replicon species are rejoined. However the Restriction is maintained as to species of promoter and reporter.

Newly submitted claim 95 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claims as recited in the Restriction Election recite a patentably distinct species (SEQ ID NO:1).

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, SEQ ID NO:1 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 10, 11, 12, 20, 21 recite nonelected species just like claims 49, 52, 53, 63, 64, 65 and are withdrawn.

Thus, claims 1, 3, 4, 5, 6, 7, 8, 9, 13-15, 16, 17, 28-31, 32, 45-48, 50, 51, 54-62, 66-69, 93, 95 and 96 are pending and under consideration.

# Claim Rejections - 35 USC § 103

# **WITHDRAWN**

Claims 1, 32, 59, 61, 62, 66 were rejected under 35 U.S.C. 103(a) as being unpatentable

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over Shi et al. in view of Hicks.

Claims 67, 68, 69 were further rejected under 35 U.S.C. 103(a) as being unpatentable over Shi et al. and Hicks in view of Khromykh et al.

Applicant submits that Shi et al. is not a prior art document after submitted a 1.132 declaration.

Applicant's arguments are considered and found persuasive.

The rejections dependent on Shi et al. are withdrawn.

Claim 1, 32, 45, 50, 51, 54, 55, 57, 93 were rejected under 35 U.S.C. 103(a) as being unpatentable over Khromykh et al. in view of Chambers et al. supported by Barrett.

Claims 47, 48, 56, 58 were rejected under 35 U.S.C. 103(a) as being unpatentable over Khromykh et al. and Chambers et al. supported by Barrett et al. in view of Hicks.

Applicant submits that the references either alone or in combination do not teach or suggest every element of the claimed invention: 1.) none of the cited references teach or suggest a reverse genetics system for screening and identifying antiflaviral compounds as recited in claim 1; 2) Khromykh et al. relates to an entirely different flavivirus; 3) and 4) Chambers also relates to different flaviviruses; 5) Hicks et al. does not teach or suggest introduction of GFP; 6) the rejection was made using hindsight reconstruction.

Applicant's arguments in regards to points 2-5 are considered and found persuasive.

The rejection is withdrawn.

Claims 1, 32 and 59 were rejected under 35 U.S.C. 103(a) as being unpatentable over Hurrelbrink et al. in view of Chambers et al. supported by Barrett.

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Claims 61, 62 and 66 were rejected under 35 U.S.C. 103(a) as being unpatentable over Hurrelbrink et al. and Chambers et al. supported by Barrett in view of Hicks et al..

Claims 67, 68, 69 were rejected as being unpatentable over Hurrelbrink et al., Chambers et al, supported by Barrett, Hicks et al. in view of Khromykh et al.

Applicant submits: 1) it would not have been obvious to extend the results of Chambers, Barrett, Hicks and Khromykh either along or in combination, to arrive at the present invention, for which Hurrelbrink does not cure the defect and Chambers involves a deletion and substitution of premembrane and envelope protein genes thus, it is inappropriate to extrapolate the construction of one flavivirus to another when one considers the difficulties encountered in cloning flaviviruses; 2) the rejection was made using hindsight reconstruction.

Applicant's arguments in regards to point 1 are considered and found persuasive.

The rejection is withdrawn.

# Claim Rejections - 35 USC § 102

#### MAINTAINED

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 was rejected under 35 U.S.C. 102(b) as being anticipated by Chambers et al.

Claim 1 was also rejected under 35 U.S.C. 102(b) as being anticipated by Lai et al.

Claim 1 was also rejected under 35 U.S.C. 102(b) as being anticipated by Yamshchikov et al.

Applicant submits that Chambers does not disclose or suggest using the chimeric YR/JE viruses for screening or identifying antiflaviviral compounds; Lai does not disclose or suggest that dengue chimers are useful for screening and/or identifying antiflaviviral compounds; Yamshchikov et al. does not disclose or suggest that WN replicons are useful for screening and/or identifying antiflaviviral compounds; thus, there is no teaching or suggestion of a system for screening and identifying antiflaviviral compounds or antiviral therapy.

Applicant's arguments are considered but found unpersuasive.

Chambers et al., Lai et al, Yamshchikov et al. teach reverse genetics systems. The claim recitation to a purpose of "for screening and identifying antiviral compounds" is interpreted as a statement of intended use that does not structurally limit the product, reciting a reverse genetics system. Further, the cited references teach reverse genetics systems for viral replication and pathogenesis, which can be used in screening processes for antivirals.

The rejection is maintained for reasons of record.

# Claim Rejections - 35 USC § 112

#### **NEW**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 46, 60, 95, 96 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 46, 60, 95, 96 recite wherein the clones and genome are "according to" SEQ ID NO:2.

It is not clear what applicant intends for the relationship between the clones and genome and SEQ ID NO: 2 to be: comprising, consisting of, homologous, or having a certain percent identity to the sequence, or nucleotide by nucleotide correspondence with the entire sequence.

# Claim Rejections - 35 USC § 103

# NEW rejections and NEW rejections necessitated by amendment

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 5, 7, 13, 14, 16, 32, 59, 61, 62, 66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hurrelbrink et al., Xiang et al., Puri et al., Yamshchikov et al. and Mishin et al.

Claim 1 recites a reverse genetics system.

Claims 3, 5, 7, 13, 14 recite the system of claim 1 comprising a full length lineage I WNV cDNA clone; wherein the cDNA comprises a promoter and a reporter; further comprising a viral promoter; further comprising a T7 viral promoter.

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Claim 16 recites a recombinant plasmid comprising claim 5.

Claim 32 recites a plasmid comprising a WNV lineage I cDNA sequence further comprising a promoter and a reporter.

Claim 59 recites a DNA molecule encoding a full length and fully infectious mRNA of lineage I WNV genome, comprising a promoter; a reporter at said 3' end.

Claims 61, 62, 66 recite the DNA molecule of claim 59 wherein said reporter is GFP; promoter is T7.

Hurrelbrink et al. teaches full length cDNA of a flavivirus (here, MVE virus) as well as inclusion of a T7 promoter as well as the use of immunofluorescence assays for detection (p. 3115, 3118).

Hurrelbrink et al. does not teach the lineage I WNV or inclusion of a reporter gene.

Xiang et al. teaches full length flavivirus Hepatitis G cDNA (p. 9125).

Puri et al. teaches full length flavivirus Dengue cDNA clone (p. 57).

Yamschikov et al. teaches full length flavivirus WNV lineage II cDNA (p. 294).

Mishin et al. teaches another flavivirus (JEV) full length cDNA as well as use of reporter gene (luciferase) to detect expression (p. 113, 115).

One of ordinary skill in the art at the time the invention was made would have been motivated to construct a full length WN lineage I cDNA with a reporter gene because Hurrelbrink et al., Xiang et al., Puri et al., Friebe et al., and Mishin et al. all teach construction of flavivirus infectious full length cDNA (Yamshchikov et al., further teaching full length WN cDNA), thus it would have been obvious to one of ordinary skill in the art to create a cDNA clone for WNV lineage I as well; and Mishin et al. teaches that incorporation of the reporter gene

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connotes expression, a functional equivalent for detection of expression. See MPEP 2144.06.

One of ordinary skill in the art at time the invention was made would have had a reasonable expectation of success to construct a full length WN lineage I cDNA with a reporter gene because Hurrelbrink et al. Xiang et al. Puri et al. Friebe et al., and Mishin et al. all teach flavivirus infectious full length cDNA (Yamshchikov et al., further teaching full length WN cDNA) and detection.

Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

Claims 1, 3, 5, 7, 8, 13, 14, 15, 16, 28, 32, 59, 61, 62, 66, 67, 68, 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hurrelbrink et al., Xiang et al., Puri et al., Yamshchikov et al. and Mishin et al. in further view of Zhu et al.

See the recitations to claims 1, 3, 5, 7, 13, 14, 16, 32, 59, 61, 62, 66 above.

Claim 8, 15, 28, 67, 68, 69 recite a second reporter; further comprising an IRES.

See the teachings of Hurrelbrink et al., Xiang et al., Puri et al., Yamshchikov et al. and Mishin et al. above.

Hurrelbrink et al., Xiang et al., Puri et al., Yamshchikov et al. and Mishin et al.do not teach a second reporter further comprising an IRES.

Zhu et al. teaches plasmids comprising dual reporter systems comprising IRES linking two GFPs for improved detection and process monitoring for cells transfected with complex constructs (p. 51).

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One of ordinary skill in the art at the time the invention was made would have been motivated to combine the construct of Hurrelbrink et al., Xiang et al., Puri et al., Yamshchikov et al. and Mishin et al. and the dual reporter/IRES system of Zhu et al. because Zhu et al. teaches enhanced detection for constructs transfected into cells.

One of ordinary skill in the art at time the invention was made would have had a reasonable expectation of success for using the construct of Hurrelbrink et al., Xiang et al., Puri et al., Yamshchikov et al. and Mishin et al. with the dual GFP/IRES system of Zhu et al. because Hurrelbrink et al., Xiang et al., Puri et al., Yamshchikov et al. and Mishin et al. and Zhu et al. teach expression of constructs in cells.

Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

Claims 1, 3, 5, 7, 8, 13, 14, 15, 16, 28, 30, 31, 32, 59, 61, 62, 66, 67, 68, 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hurrelbrink et al., Xiang et al., Puri et al., Yamshchikov et al. and Mishin et al. in view of Zhu et al. in further view of Varnavski et al.

See the recitations to claims 1, 3, 5, 7, 8, 13, 14, 15, 16, 28, 32, 59, 61, 62, 66, 67, 68, 69 above.

Claim 30, 31 further recite linkage of reporters by an autoprotease nucleotide sequence from foot and mouth disease virus 2a autoprotease nucleotide sequence.

See the teachings of Hurrelbrink et al., Xiang et al., Puri et al., Yamshchikov et al. and Mishin et al. in view of Zhu et al. above.

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Hurrelbrink et al., Xiang et al., Puri et al., Yamshchikov et al. and Mishin et al. in view of Zhu et al. do not teach incorporation of an autoprotease 2a sequence.

Varnavski et al. teaches a unique site comprising 2a autoprotease of FMD in order to improve cleavage and expression of heterologous genes including GFPs (pp. 366-368).

One of ordinary skill in the art at the time the invention was made would have been motivated to combine the construct of Hurrelbrink et al., Xiang et al., Puri et al., Yamshchikov et al. and Mishin et al. in view of Zhu et al. and the autoprotease sequence of Varnavski et al. because Varnavski et al. teaches a added, conferred benefit of improved cleavage and expression of heterologous genes such as GFPs in flavivirus constructs.

One of ordinary skill in the art at time the invention was made would have had a reasonable expectation of success for using the construct of Hurrelbrink et al., Xiang et al., Puri et al., Yamshchikov et al. and Mishin et al. in view of Zhu et al. with the autoprotease of Varnavski et al. because both Hurrelbrink et al., Xiang et al., Puri et al., Yamschhikov et al. and Mishin et al. Varnavski et al. teach construction and expression of flaviviral constructs.

Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

Claims 45, 47, 48, 50, 51, 54, 55, 56, 57, 58, 93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chambers et al. supported by Barrett in view of Hurrelbrink et al. Xiang et al., Puri et al. Friebe et al., Yamschchikov et al. and Mishin et al. in view of Zhu et al.

Claim 45 recites a DNA molecule comprising a DNA sequence encoding a mRNA of lineage I WNV genome; having a 5' and 3' end; adapted to report the transcription of said DNA

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sequence comprising; a deletion corresponding to one or more structural genes of said lineage I WNV genome; a promoter at 5' end; a nucleotide sequence encoding a reporter at the 3' end.

Claim 50, 51, 54 recite the DNA molecule of claim 45 with GFP; wherein structural deletions are in the envelope; further comprising a T7 promoter.

Claim 47, 48, 55, 56, 57, 58 recite the DNA molecule of claim 45 with GFP.

Claim 93 recites a cell line comprising the molecule.

Chambers et al. teaches flavivirus cDNA backbones (here, JEV) wherein structural proteins are deleted and replaced with proteins of other flaviviruses (nonetheless teaching deletions of structural envelope proteins); with T3 promoters (Here the promoter is asserted to be functionally equivalent to T7 promoter. See MPEP 2144.06.) as well as cells comprising them. Barrett is cited for teaching the applicability to WNV as well as structural similarity among flaviviruses.

Chambers et al. supported by Barrett does not teach WNV lineage I or GFP.

See the teachings of Hurrelbrink et al. Xiang et al., Puri et al. Friebe et al., Yamschchikov et al. and Mishin et al. in view of Zhu et al. above, indicating construction of flavivirus cDNAs.

One of ordinary skill in the art at the time the invention was made would have been motivated to construct a full length WN lineage I cDNA with envelope deletions because Chambers et al. teaches flavivirus cDNA backbones comprising envelope deletions for insertion and incorporation of structural proteins, high attenuation and high immunogenicity; Hurrelbrink et al. Xiang et al. Puri et al. Friebe et al., and Mishin et al. in view of Zhu et al. all teach flavivirus infectious full length cDNA, and Barrett et al. teaches the Chambers et al. technology for West Nile vaccine use.

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One of ordinary skill in the art at time the invention was made would have had a reasonable expectation of success to construct a full length WN lineage I cDNA comprising envelope deletions because Chambers et al., Hurrelbrink et al. Xiang et al. Puri et al. Friebe et al., and Mishin et al. in view of Zhu et al. all teach flavivirus infectious full length cDNA and Barrett et al. cited in support all teach the technology for use in structurally similar flaviviruses.

Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

Claims 1, 4, 6, 7, 13, 14, 17, 30, 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Varnavski et al. in view of Pang et al, Khromykh et al., Friebe et al., and Yamschikov et al.

Claim 1 recites a reverse genetics system.

Claims 4, 6, 7, 13, 14, recite the system of claim 1 comprising a lineage I WNV replicon; wherein the replicon comprises a promoter sequence and a first reporter; wherein the reporter is GFP; wherein the promoter is a viral promoter; wherein the promoter is a T7 promoter.

Claim 17 recites a recombinant plasmid comprising the replicon.

Claims 30, 31 recite the system wherein the reporters are linked by an autoprotease nucleotide sequence; wherein the autoprotease is a FMD virus 2a.

Varnavski et al. teaches flavivirus (here, Kunjin) subgenomic replicons, a reverse

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genetics system; from corresponding plasmids; a reporter gene (GFP); viral promoters (here, SP6; however, the promoter is asserted to be functionally equivalent); as well as the autoprotease 2A sequence of FMD (pp. 366-370).

Varnavski et al. does not teach a WNV lineage I replicon or incorporation of IRES.

Pang et al. teaches flavivirus Dengue replicons; Khromykh et al. teaches flavivirus Kunjin replicons and close structural relation with other flaviviruses; Friebe et al. teaches flavivirus HCV replicons (p. 10247); Yamschikov et al. teaches West Nile lineage II replicons.

Friebe et al. also teaches that incorporation of the IRES in flavivirus RNA enhances direct binding of the 40S ribosome subunit in the absence of additional translation factors (p. 12047).

One of ordinary skill in the art at the time the invention was made would have been motivated to construct a WN lineage I replicon with an additional IRES element because Varnavski et al., Pang et al., Khromykh et al., Friebe et al., all teach flavivirus replicons (Yamshchikov et al., further teaching WN virus replicons), Khromykh et al. teaches close relation, and Friebe et al. teaches that incorporation of the IRES RNA sequence confers added benefit by enhancing translation.

One of ordinary skill in the art at time the invention was made would have had a reasonable expectation of success for construct a WN lineage I replicon with an additional IRES element because Varnavski et al., Pang et al., Khromykh et al., Friebe et al., and Yamshchikov et al. all teach flavivirus replicons and Khromykh et al. teaches structural similarity among the

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closely related viruses.

Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

Claims 1, 4, 6, 7, 9, 13, 14, 15, 17, 29, 30, 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Varnavski et al. in view of Pang et al, Khromykh et al., Friebe et al., and Yamschikov et al. in further view of Zhu et al.

See the recitations to claims 1, 4, 6, 7, 13, 14, 17, 30, 31 above.

Claims 9, 15, 29, further recite the system of claim 6 wherein the replicon further comprises a second reporter and IRES.

See the teachings of Varnavski et al. in view of Pang et al, Khromykh et al., Friebe et al., and Yamschikov et al. above.

Varnavski et al. in view of Pang et al, Khromykh et al., Friebe et al., and Yamschikov et al. do not teach a second reporter or incorporation of IRES.

See the teachings of Zhu et al. above.

One of ordinary skill in the art at the time the invention was made would have been motivated to construct a WN lineage I replicon comprising a second reporter and IRES because Varnavski et al., Pang et al., Khromykh et al., Friebe et al., all teach flavivirus replicons (Yamshchikov et al., further teaching WN virus replicons), Khromykh et al. teaches close relation, and because Zhu et al. teaches enhanced detection for constructs transfected into cells.

One of ordinary skill in the art at time the invention was made would have had a

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reasonable expectation of success to construct a WN lineage I replicon comprising a second reporter and IRES because Varnavski et al., Pang et al., Khromykh et al., Friebe et al., and Yamshchikov et al. all teach flavivirus replicons and Zhu et al. teach expression of constructs in cells.

Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, absent unexpected results to the contrary.

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Conclusion

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to M. Franco Salvoza whose telephone number is (571) 272-8410.

The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the

organization where this application or proceeding is assigned is 571-273-8300.

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M. Franco Salvoza

Patent Examiner

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PRIMARY EXAMINER